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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| FLORY, CHRISTOPHER A | |
| ART UNIT | PAPER NUMBER |
| 3762 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/700,368 | PASTORE ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTOPHER A. FLORY | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2009*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8-11,13-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8-11,13-16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 January 2009 has been entered.

### *Response to Arguments*

2. Applicant's arguments with respect to claims 1, 4-8, 11, 14-16 and 18 as anticipated under §102(e) by Hill'208 have been considered but are moot in view of the new ground(s) of rejection.

3. Applicant's arguments filed 15 January 2009 have been fully considered but they are not persuasive. Claims 1, 3-6, 8-11, 13-16 and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Adams'380 in view of Gross'909.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant continues to only addresses the Adams'380 reference. In the combination of Adams'380 and Gross'909 clearly discloses measurement of cardiac

output and patient exertion level and adjusts parasympathetic stimulation based on these computations as explained in the paragraphs below.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies, i.e., that parasympathetic stimulation would be delivered at the same time that ventricular paces are being delivered, are not and cannot be recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This limitation was discussed previously and removed because it was found that there is no support in the disclosure of the instant application for simultaneous delivery. The claim language simply recites "ventricular pacing therapy in conjunction with parasympathetic stimulation," wherein "in conjunction with" does not require or even imply simultaneous delivery.

Regarding Applicant's argument that all of the cited references teach parasympathetic stimulation for the express purpose of decreasing heart rate and not cardiac output, it is first noted that the mathematical and inherent correlations between the two have been previously discussed. Additionally, it is noted that in at least Gross'909 parasympathetic therapy to affect cardiac output is explicitly disclosed in the cited portions of the reference, with particular emphasis on paragraphs [63], [64], [135] and [207].

4. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4-6, 8, 11, 14-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US 6,718,208, hereinafter Hill'208), or alternatively in view of Gross'909.

Regarding claims 1, 4, 11 and 14, Hill'208 discloses an implantable device for delivering cardiac function therapy (abstract) comprising a plurality of pacing channels for delivering pacing pulses to multiple ventricular sites (abstract; column 6, lines 26-47; also column 15, lines 48-50); a parasympathetic stimulation channel for stimulating parasympathetic nerves (column 5, line 55 through column 6, line 19; column 7, line 62 through column 8, line 17); a sensor for measuring cardiac output (column 4, lines 35-44); a controller for controlling the delivery of pacing pulses to multiple ventricular sites (Fig. 1, controller 30; abstract; column 6, lines 26-47); wherein the controller delivers the

ventricular pacing to prevent the heart rate slowing below a specified minimum value (abstract); wherein it is taken that the controller modulates delivery of parasympathetic stimulation in accordance with the cardiac output measurement (column 6, lines 9-19). It is noted that although Hill'208 does not expressly disclose multiple ventricular pacing cites, it does disclose that the ventricle is paced as is well known in the field, and it is considered that multiple-site ventricular pacing is certainly well known in the field as evidenced by the numerous references cited in the instant application both by the Examiner and the Applicant showing pacing leads with more than one electrode positioned in the ventricle or ventricles.

Further regarding claims 1 and 11, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Hill'208 which increases heart rate also inherently decreases wall stress. Alternatively, Hill'208 teaches of a controller for controlling the delivery of pacing pulses to pacing sites in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see above), which Examiner interprets to be capable of reducing ventricular wall stress given that the Hill'208 device meets all the structural limitations set forth in the instant claims.

Additionally, Hill'208 is considered to disclose relating exertion levels to minimum cardiac output via its connection to minimal or target heart rate and to cease delivery of parasympathetic stimulation if cardiac output falls below a minimum level in the

Abstract; column 2, lines 41-44, column 4, lines 35-44 and column 6 lines 17-20. Alternatively, in the same field of endeavor, Gross'909 teaches halting or limiting/delaying vagal stimulation, i.e. parasympathetic stimulation, in order to achieve a desired target rate based on configuration of values including cardiac output (paragraph [207]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hill'208 to halt vagal stimulation as taught by Gross'909, to provide Hill'208 with the same advantage of achieving a target or desired rate based on cardiac output variables.

Regarding claims 5, and 15, and further regarding claims 1 and 11, Hill'208 discloses delivery of parasympathetic stimulation in response to a heart rate condition sensed by electrodes 210 and 220 in Fig. 2, wherein it is contemplated that heart rate is an indicator of a patient's exertion level. Hill'208 discloses delivering nerve and pacing stimulation to return the heart to a normal cardiac output, or maintain a normal cardiac output (column 4, lines 32-44), wherein a normal cardiac output is considered to be indicative of the adequacy of the cardiac output.

Regarding claims 6 and 16, Hill'208 discloses delivering parasympathetic stimulation when the heart is in a slowed or stopped condition (abstract), wherein a slowed or stopped condition is representative of being below a specified exertion limit value when heart rate is taken to be a sensed indication of exertion.

Regarding claims 8 and 18, Gross'909 explicitly teaches using a look-up table to compute cardiac output values relative to patient activity (paragraphs [64], [135], [207], [227]).

7. Claims 1, 3-6, 8-11, 13-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. 2003/0229380, hereinafter Adams'380) in view of Gross et al. (US 2003/0045909, hereinafter Gross'909).

In regards to claims 1 and 11, Adams'380 discloses an implantable device and method for delivering cardiac function therapy to a patient with multiple electrodes (see for example paragraphs 2, 9 and 12), in which includes and an embodiment comprising a biventricular pacing system (see for example paragraph 55), which is interpreted by Examiner to inherently include multiple pacing channels since the system comprises pacing at multiple sites. Adams'380 also discloses that the device comprises a parasympathetic stimulation system (see for example paragraph 11), which Examiner interprets as including a parasympathetic stimulation channel.

Further regarding claims 1 and 11, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Adams'380 which increases heart rate (ABSTRACT; paragraphs [5], [6]) also inherently decreases wall stress. Alternatively, Adams'380 teaches of a controller for controlling the delivery of pacing pulses to pacing sites (see for example paragraph 10), in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see for example paragraph 11), which Examiner interprets to be capable of reducing ventricular wall stress given that the Adams'380 device meets all the structural limitations set forth in the instant claims.

Still further regarding claims 1 and 11, Adams'380 is held to disclose a device capable of delivering stimulation simultaneously, as it meets all of the structural limitations set forth in the claims of the instant application. Alternatively, it would have been obvious to one of ordinary skill in the art at the time of the invention to delivery the therapies in a synchronous manner, since synchronous pacing therapy as well as synchronous pacing and nerve stimulating therapies are well known in the implantable stimulator art.

Still further regarding claim 1, Adams'380 discloses the invention substantially as claimed, but does not expressly disclose parasympathetic stimulation in conjunction with the ventricular pacing stimulation. However, in the same field of endeavor, Gross'909 teaches coupling a parasympathetic nerve stimulation device with an implanted deice for monitoring and correcting the heart rate, e.g. a bi-ventricular pacemaker, in order to increase the heart rate when heart rate is too low (paragraphs [9] and [193]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Adams'380 with the combined stimulation as taught by Gross'909 to provide the Adams'380 invention with the same advantage of being able to selectively increase heart rate with an implanted pacemaker to compensate for a drop in heart rate caused by parasympathetic stimulation.

Still further regarding claim 1, Adams'380 discloses a sensor for measuring cardiac output (see for example paragraphs 10 and 92), wherein the controller is programmed to modulate the delivery of parasympathetic stimulation in accordance with the measured output (see for example paragraphs 11, 42 and 46). Alternatively,

Gross'909 teaches a sensor for measuring cardiac output and modulating the delivery of parasympathetic stimulation in accordance with the cardiac output (paragraphs [9], [63], [98], [193], [215]).

In regards to claims 4 and 14, Adams'380 discloses slowing the heart rate of a patient by parasympathetic stimulation (see for example paragraphs 38 and 39).

In regards to claims 5, 8, 15 and 18, and further regarding claims 1 and 11, Adams'380 discloses monitoring a patient's blood pressure, and the use of an activity sensor for monitoring a patient's exertion level (see for example paragraphs 46, 55 and 64). It is taken that the parameter computed form exertion level and cardiac output is indicative of the adequacy of the cardiac output (paragraphs [9], [63], [98], [193], [215]).

Further regarding claims 8 and 18, Gross'909 explicitly teaches using a look-up table to compute cardiac output values relative to patient activity (paragraphs [64], [135], [207], [227]).

In regards to claims 3 and 13, although Adams'380 teaches of the use of a sensor/circuit for measuring impedance to detect cardiac output (see for example paragraph 46), Adams'380 does not specifically teach of the use a trans-thoracic impedance measuring sensor/circuit. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams'380 to include a trans-thoracic impedance to measure cardiac output, since this type of impedance sensor/circuit is well known in the art as a efficient and effective detector of cardiac output. Alternatively, Gross'909 teaches

impedance cardiography, which is taken to include trans-thoracic impedance measurement (paragraphs [97], [215]).

In regards to claims 6 and 16, Adams'380 teaches of the system providing parasympathetic stimulation when the activity level is below a particular value (see for example paragraph 46). Although Adams'380 does not specifically state that parasympathetic stimulation only when the measured activity level is below a particular value, Examiner takes the position that such a requirement would have been an obvious modification to one having ordinary skill in the art at the time of the invention since Adams'380 teaches that it is desirable to induce parasympathetic stimulation to reduce a patient's heart rate (see for example paragraph 11) when the activity level is stabilized (see for example paragraph 46), in order to provide effective and efficient parasympathetic stimulation.

In regards to claims 9 and 19, Adams'380 does not specifically state the use of a minute ventilation sensor or an accelerometer, for an exertion level sensor; however, Adams'380 does teach that the activity sensor can be one of a multiple types of exertion/metabolic level sensors (see for example paragraph 64). Thus, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams'380 to include a minute ventilation sensor, since these are commonly known activity/exertion sensors that can be used to efficiently and effectively measure a patient's metabolic demand.

Regarding claims 10 and 20, Gross'909 discloses that the exertion sensor is an accelerometer for measuring the motion of the subject (paragraphs [95], [193]).

8. Claims 3, 9, 10, 13, 19 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hill'208.

In regards to claims 3 and 13, Hill'208 teaches of the use of a sensor/circuit for measuring impedance to detect cardiac output as explained above, Hill'208 does not specifically teach of the use a trans-thoracic impedance measuring sensor/circuit. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Hill'208 to include a trans-thoracic impedance to measure cardiac output, since this type of impedance sensor/circuit is well known in the art as a efficient and effective detector of cardiac output.

In regards to claims 9, 10, 19 and 20, Hill'208 does not specifically state the use of a minute ventilation sensor or an accelerometer for an exertion level sensor. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught Hill'208 to include a minute ventilation sensor or accelerometer, since these are commonly known activity/exertion sensors that can be used to efficiently and effectively measure a patient's metabolic demand.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

25 February 2009

/George Manuel/
Primary Examiner